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Hubert H. Lim

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EXAMINER

PORTER, JR, GARY A

ART UNIT

PAPER NUMBER

3766

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/592,916	<b>Applicant(s)</b> LIM ET AL.	
	<b>Examiner</b> GARY A. PORTER, JR	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figure 2 is of insufficient quality to extract any significant meaning therefrom. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the wireless connection from the current stimulator to at least one electrode (Claims 20 and 33) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

Art Unit: 3766

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not recite wirelessly transmitting the stimulation sequence from the current stimulator to at least one stimulating electrode (Claims 20 and 33).

### ***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-23 and 39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Specifically in regards to Claims 1, 16 and 39, Applicant claims "at least one stimulating electrode disposed in the inferior colliculus of a mammal...." This statement effectively claims a physical body part of a mammal, which is non-statutory. To overcome this rejection, the Examiner suggests modifying the claim language to read

Art Unit: 3766

"at least one stimulating electrode adapted to be placed in the inferior colliculus of a mammal...."

Regarding Claim 16, Applicant further claims "a current stimulator that is implanted in a mammal...." To overcome this rejection, the Examiner suggests modifying the claim language to read "a current stimulator that is adapted to be implanted in a mammal."

With regards to Claim 21, Applicant claims "...are held together magnetically across a biological membrane of the mammal." To overcome this rejection, the Examiner suggests modifying the claim language to read "...are adapted to be held together magnetically across a biological membrane of the mammal."

Claims 2-15, 17-20, 22 and 23 are also rejected under 35 U.S.C. 101 since they are dependent on claims exhibiting non-statutory subject matter as described above.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-10, 15, 24, 25, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson et al. (US Pub. 2005/0004627).

7. Regarding Claims 1 and 24, Gibson discloses an auditory prosthesis system and a method of use comprising a microphone (Section [0103]), a sound processor (Section

Art Unit: 3766

[0103]) and a current stimulator 21 (Section [0096]). Gibson further discloses an electrode array that is implantable within the inferior colliculus (Abstract), wherein the electrode array comprises an elongate member 11, i.e. shank, having a plurality of electrodes 12, i.e. stimulation sites (Fig. 1). Gibson does not explicitly disclose the system has at least two shanks with multiple stimulation sites. However, Gibson does implicitly disclose that multiple electrode arrays can be implanted within the inferior colliculus of a patient (Section [0052]; Claim 47). Gibson does not explicitly state why multiple electrode arrays are used, but it appears that multiple electrode arrays are used to provide stimulation to the different frequency layers of the inferior colliculus (Section [0084]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Gibson, with multiple implantable electrode arrays as suggested by Gibson, since such a modification would provide the system with multiple electrode arrays that would provide stimulation to the different frequency layers of the inferior colliculus.

8. In regards to Claim 2, Gibson discloses each shank is between 2 and 6 millimeters in length (Section [0018]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the length of each shank range from 3 to 7 millimeters in length, since it has been held that where the claimed ranges overlap or lie inside ranges disclosed by the prior art, a *prima facie* case of obviousness exists. *In re Wertheim*, 191 USPQ 90.

9. With regards to Claim 3, Gibson discloses that each shank has between 4 and 80 stimulation sites (Section [0015]). Gibson does not explicitly disclose the system has

Art Unit: 3766

five shanks with multiple stimulation sites. However, Gibson does implicitly disclose that multiple electrode arrays can be implanted within the inferior colliculus of a patient (Section [0052]; Claim 47). Gibson does not explicitly state why multiple electrode arrays are used, but it appears that multiple electrode arrays are used to provide stimulation to the different frequency layers of the inferior colliculus (Section [0084]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Gibson, with multiple implantable electrode arrays as suggested by Gibson, since such a modification would provide the system with multiple electrode arrays that would provide stimulation to the different frequency layers of the inferior colliculus.

10. Regarding Claim 4, Gibson discloses the electrodes on the elongate members are spaced from 50 to 2000 microns apart (Section [0018]).

11. In regards to Claims 5 and 6, Gibson discloses an electrode array with an elongate member 11, i.e. a shank, that is 2 to 6 millimeters in length (Section [0018]; see rejection of Claim 2). The shank comprises 4 to 80 electrodes, i.e. stimulation sites (Section [0015]; see rejection of Claim 5) and the electrodes are spaced from 50 to 2000 microns apart (Section [0018]; see rejection of Claim 4). Gibson further discloses the width of the electrodes are from 50 to 2000 microns. Gibson does not disclose the particular geometry of the electrodes (does not disclose the specific surface area of the electrodes). However, Gibson does disclose that the electrodes preferably have a surface area sufficiently large so as not to exceed charge density limits (Section [0017]). It would have been obvious to one having ordinary skill in the art at the time the

Art Unit: 3766

invention was made to make the surface area of the electrodes between 400 to 4000 square microns or, more specifically, 2000 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

12. With regards to Claims 7 and 8, Gibson discloses an electrode array having 4 to 80 electrodes and each electrode is spaced 50 to 2000 microns apart (Section [0015, 0018]). Gibson does not explicitly disclose the system has five shanks with multiple stimulation sites. However, Gibson does implicitly disclose that multiple electrode arrays can be implanted within the inferior colliculus of a patient (Section [0052]; Claim 47). Gibson does not explicitly state why multiple electrode arrays are used, but it appears that multiple electrode arrays are used to provide stimulation to the different frequency layers of the inferior colliculus (Section [0084]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Gibson, with multiple implantable electrode arrays as suggested by Gibson, since such a modification would provide the system with multiple electrode arrays that would provide stimulation to the different frequency layers of the inferior colliculus.

13. Regarding Claims 9 and 10, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or

Art Unit: 3766

functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Gibson discloses an electrode array with an elongate member 11 that contains multiple electrodes or stimulation sites. The length of the shank, the number of electrodes and the spacing of electrodes as disclosed by Applicant are all taught by Gibson (Sections [0015, 0018]). Specifically in regards to Claim 9, Gibson specifically discloses that the spacing of the electrodes is preferably such that different frequency layers of the inferior colliculus can be stimulated (Section [0084]). Additionally, since Gibson discloses multiple elongate members can be implanted (Claim 47) and that the configuration of an individual elongate member is “preferably such that different frequency layers of the inferior colliculus can be stimulated”, the auditory prosthesis system of Gibson is inherently configured to stimulate different locations within the same isofrequency lamina.

14. In regards to Claim 15, Gibson teaches the current stimulator 21 comprises an induction coil (Section [0101]).

15. In regards to Claims 25 and 27, Gibson discloses all of the claimed invention except for specifically stating a stimulating electrode is inserted in such a way as to be aligned along a tonotopic axis of the central nucleus. However, Gibson does state that the array has an specific electrode spacing in order to stimulate the different frequency layers of the inferior colliculus and that it is implanted in the inferior colliculus in order to successfully stimulate those layers (Section [0084]). Since the underlying layers can only be successfully stimulated if the array is aligned in a manner to contact every

Art Unit: 3766

frequency layer and since the electrodes are on a single elongate member, the array is inherently going to be placed perpendicular to at least one isofrequency lamina since Gibson's disclosure states that multiple layers are stimulated and in contact with the array and the underlying layers can only be successfully stimulated if the array is aligned in a manner to contact every frequency layer.

16. With regards to Claim 28, Gibson discloses an electrode array with an elongate member 11 that contains multiple electrodes or stimulation sites. The length of the shank, the number of electrodes and the spacing of electrodes as disclosed by Applicant are all taught by Gibson (Sections [0015, 0018]). Furthermore, Gibson specifically discloses that the spacing of the electrodes is preferably such that different frequency layers of the inferior colliculus can be stimulated (Section [0084]).

Additionally, since Gibson discloses multiple elongate members can be implanted (Claim 47) and that the configuration of an individual elongate member is "preferably such that different frequency layers of the inferior colliculus can be stimulated", the auditory prosthesis system of Gibson is inherently configured to stimulate different locations within the same isofrequency lamina.

17. Claims 11-13, 16-23, 26 and 29-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson et al. (US Pub. 2005/0004627) in view of Milojevic et al. (US Pub. 2005/0033377).

18. Regarding Claims 11, 12, 16, 22, 23 and 39, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

Art Unit: 3766

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Gibson discloses an auditory prosthesis system comprising a microphone (Section [0103]), a sound processor (Section [0103]) and a current stimulator 21 (Section [0096]) with a receiver (Section [0101]). Gibson further discloses an electrode array that is implantable within the inferior colliculus (Abstract), wherein the electrode array comprises an elongate member 11, i.e. shank, having a plurality of electrodes 12, i.e. stimulation sites (Fig. 1). Gibson does not explicitly disclose the system has at least two shanks with multiple stimulation sites. However, Gibson does implicitly disclose that multiple electrode arrays can be implanted within the inferior colliculus of a patient (Section [0052]; Claim 47). Gibson does not explicitly state why multiple electrode arrays are used, but it appears that multiple electrode arrays are used to provide stimulation to the different frequency layers of the inferior colliculus (Section [0084]). Additionally, Gibson discloses that the speech processor of the auditory prosthesis encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms developed for cochlear implant systems (Section [0103]; emphasis added). Gibson does not explicitly state what algorithm is followed to process the sound signals. However, Milojevic teaches a process of transforming detected sound into a stimulation sequence to be applied to a patient (Abstract), wherein a specific stimulation target is

Art Unit: 3766

the inferior colliculus (Section [0045]). Furthermore, Milojevic teaches the well known process of converting detected sound to electrical stimulation in cochlear implants where the sound signal is encoded in a train of electrical pulses that carry frequency and time information (Section [0027]). Lastly, Milojevic teaches that the stimulus signal is applied to the prosthesis differentially, more specifically by current steering for the purpose of producing and/or releasing naturally occurring agents into the neural network to influence and preferably enhance the neural plasticity thereof(Section [0338]). The Examiner notes that current steering is defined as shifting stimulation from one electrode to another in an overlapping fashion (Section [0182]). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Gibson reference to include a multi-shank auditory prosthesis system, as taught and suggested by Gibson, and to include the capability of differentially extracting one or more frequency components of a sound wave and differentially stimulating via current steering, one or more regions of the inferior colliculus, as taught and suggested by Milojevic, for the purpose of increasing the stimulation area of the inferior colliculus and of producing and/or releasing naturally occurring agents into the neural network to influence and preferably enhance the neural plasticity thereof.

19. Regarding Claims 26, 29, 35, 36 and 40, Gibson discloses an auditory prosthesis system comprising a microphone (Section [0103]), a sound processor (Section [0103]) and a current stimulator 21 (Section [0096]) with a receiver (Section [0101]). Gibson further discloses an electrode array that is implantable within the inferior

Art Unit: 3766

colliculus (Abstract), wherein the electrode array comprises an elongate member 11, i.e. shank, having a plurality of electrodes 12, i.e. stimulation sites (Fig. 1). Gibson does not explicitly disclose the system has at least two shanks with multiple stimulation sites.

However, Gibson does implicitly disclose that multiple electrode arrays can be implanted within the inferior colliculus of a patient (Section [0052]; Claim 47). Gibson does not explicitly state why multiple electrode arrays are used, but it appears that multiple electrode arrays are used to provide stimulation to the different frequency layers of the inferior colliculus (Section [0084]). Additionally, Gibson discloses that the speech processor of the auditory prosthesis encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms developed for cochlear implant systems (Section [0103]; emphasis added). Gibson does not explicitly state what algorithm is followed to process the sound signals. However, Milojevic teaches a process of transforming detected sound into a stimulation sequence to be applied to a patient (Abstract), wherein a specific stimulation target is the inferior colliculus (Section [0045]). Furthermore, Milojevic teaches the well known process of converting detected sound to electrical stimulation in cochlear implants where the sound signal is encoded in a train of electrical pulses that carry frequency and time information (Section [0027]). Lastly, Milojevic teaches that the stimulus signal is applied to the prosthesis differentially, more specifically by current steering for the purpose of producing and/or releasing naturally occurring agents into the neural network to influence and preferably enhance the neural plasticity thereof (Section [0338]). The Examiner notes that current steering is defined as shifting stimulation from one

Art Unit: 3766

electrode to another in an overlapping fashion (Section [0182]). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Gibson reference to include a multi-shank auditory prosthesis system, as taught and suggested by Gibson, and to include the capability of differentially extracting one or more frequency components of a sound wave and differentially stimulating via current steering, one or more regions of the inferior colliculus, as taught and suggested by Milojevic, for the purpose of increasing the stimulation area of the inferior colliculus and of producing and/or releasing naturally occurring agents into the neural network to influence and preferably enhance the neural plasticity thereof.

20. In regards to Claim 13, Gibson discloses all of the claimed invention except for the specific type of microphone used. However, Milojevic teaches that a directional microphone can be used in an implanted auditory prosthesis for the purpose of rejecting common mode body-conducted noise emanating from body functions (Section [0114]). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Gibson reference to include a directional microphone, as taught and suggested by Milojevic, for the purpose of rejecting common mode body-conducted noise emanating from body functions.

21. With regards to Claims 17 and 30, Gibson teaches that the sound processor on the external controller comprises an inductive coil, the current stimulator comprises an RF receiver, and the signal transmitted by the sound processor to the current stimulator is a radiofrequency signal (Section [0100-0103]).

Art Unit: 3766

22. Regarding Claims 18 and 31, Gibson teaches that the current stimulator is powered by transcutaneous induction from the sound processor (Section [0104]).

23. In regards to Claims 19 and 32, Gibson teaches the current stimulator 21 and at least one stimulating electrode are connected by wire through lead 18 (Section [0095-0096]).

24. With regards to Claims 20 and 33, Gibson in view of Milojevic discloses all of the claimed invention except for wirelessly transmitting the stimulation sequence from the current stimulator to at least one stimulating electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a wireless connection instead of a hardwired connection since the examiner takes Official Notice of the equivalence of a hardwired and wireless connection and the selection of either of these known equivalents to connect the stimulator to the electrode would be within the level of ordinary skill in the art.

25. Regarding Claims 21 and 34, Gibson teaches the transmitter portion of the sound processor and the implanted current stimulator are held together magnetically across a biological membrane of a mammal (Section [0102]).

26. In regards to Claims 37 and 38, Gibson discloses an electrode array with an elongate member 11 that contains multiple electrodes or stimulation sites. The length of the shank, the number of electrodes and the spacing of electrodes as disclosed by Applicant are all taught by Gibson (Sections [0015, 0018]). Furthermore, Gibson specifically discloses that the spacing of the electrodes is preferably such that different frequency layers of the inferior colliculus can be stimulated (Section [0084]).

Art Unit: 3766

Additionally, since Gibson discloses multiple elongate members can be implanted (Claim 47) and that the configuration of an individual elongate member is “preferably such that different frequency layers of the inferior colliculus can be stimulated”, the auditory prosthesis system of Gibson is inherently configured to stimulate different locations within the same isofrequency lamina

27. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson et al. (US Pub. 2005/0004627) in view of Milojevic et al. (US Pub. 2005/0033377), further in view of Lesinski et al. (US Patent 6,381,336). Gibson in view of Milojevic discloses all of the claimed invention except for an array of microphones. However, Lesinski teaches that an array of microphones can be used in hearing prostheses for the purpose of providing directivity of sound detection (Col. 7, lines 25-46). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Gibson in view of Milojevic reference to include a microphone array, as taught and suggested by Lesinski, for the purpose of providing improved directivity for sound detection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

Art Unit: 3766

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./  
Examiner, Art Unit 3766

/Carl H. Layno/  
Supervisory Patent Examiner, Art  
Unit 3766